

REMARKS

Claims 21-40 are pending. Claims 21, 28, 29, 34-38, and 40 are under examination, and claims 22-27, 30-33, and 39 are withdrawn as being directed to non-elected subject matter. Claims 28, 29, and 40 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form. Claims 21 and 34-38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Stürzebecher et al., DE 10029014-A1 (“Stürzebecher”).

Claim Objections

Claims 28, 29, and 40 are objected to as being dependent upon a rejected base claim. Claims 28 and 40 depend from claim 21, and claim 29 depends from claim 28. Based on the arguments presented herein, Applicants respectfully submit that claim 21 is in condition for allowance, and this ground for objection should be withdrawn.

Claim Rejection under 35 U.S.C. § 102(b)

Claims 21 and 34-38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stürzebecher. Applicants respectfully traverse this rejection.

M.P.E.P. § 2131 relates to the anticipation of claims by a prior art reference. This section clearly states that (emphasis added):

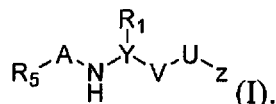
“[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, (Fed. Cir. 1987)).

Guidance relating to the anticipation of structures and compositions is also provided in M.P.E.P. § 2131 (emphasis added):

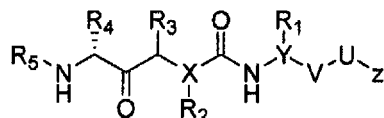
“[w]hen a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art” (citing *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001)).

For a claim to be anticipated under 35 U.S.C. § 102 by a prior art reference, the reference must teach a compound that falls within the claimed genus. Following the guidelines established in the M.P.E.P. and in the case law, Stürzebecher cannot anticipate any of instant claims 21 or 34-38.

Claim 21 recites compounds of general formula I, which has the following structure:



Formula I can also be described as follows:



The instant specification teaches that (emphasis added):

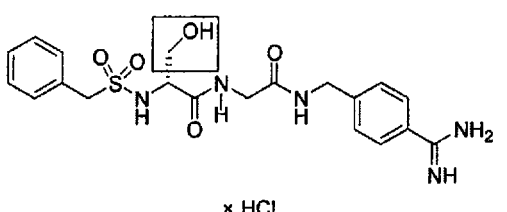
“[compounds of formula I that include] 4-amidinobenzylamine...both inhibit urokinase very effectively and are eliminated slowly from the circulation, in particular following i.v. or s.c. administration, when, in addition to the amidino function, other charged groups, preferably carboxyl, amino, amidino, hydroxyamidino, amidrazono or guanidino are introduced” (page 5, lines 17-24).

Accordingly, claim 21 further requires that the claimed compounds of formula I are:

“characterized in that one or more charged radicals, derived from $-\text{COOH}$, $-\text{CH}(\text{COOH})_2$, $-\text{SO}_2\text{H}$, NH_2 , an amidino, hydroxyamidino, amidrazono, or guanidino group, are present in the radicals R_1 , R_2 , R_3 or R_5 ...”

Pursuant to the M.P.E.P. and the case law, any compound that is cited as anticipatory by the Office must be charged in the manner required by the claims, i.e., at least one of R_1 , R_2 , R_3 , or R_5 must be charged.

In stating that Stürzebecher anticipates instant claims 21 and 34-38, the Office has cited the hydrochloride salt of benzylsulfonyl-D-Ser-Gly-amidinobenzylamide (“the Stürzebecher compound”). Analysis of the Stürzebecher compound and instant formula I shows the following correspondence:

<p>Stürzebecher compound:</p>  <p style="text-align: center;">x HCl</p>	<p>Corresponding Groups in Instant Formula I:</p> <p>$R_1 = H;$ $R_2 = H;$ $R_3 = H;$ $R_4 = -(CH_2)_fOR_{11}$, where $f=1$ and R_{11} is H; $R_5 = -SO_2R_{12}$, where R_{12} = unsubstituted aralkyl; U = phenyl; $V = (CH_2)_n$, where $n = 0$; $X = CH;$ $Y = (CH_2)_m$, where $m = 1$; and Z = occurs in the 4-position and is an amidino group $-C(NH)NHR_{14}$, where R_{14} is H.</p>
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In accord with Applicants' analysis, the Office has acknowledged that the highlighted Stürzebecher $-CH_2OH$ group is equivalent to R_4 of instant formula I (see, for example, page 2 of the Office Action). As a monohydrochloride salt, the Stürzebecher compound bears only one positive charge. If the Stürzebecher $-CH_2OH$ group bore that positive charge, R_1 , R_2 , R_3 , and R_5 must be uncharged. There is no legal basis for anticipation of the instant claims by a compound where R_4 is charged and R_1 , R_2 , R_3 , and R_5 are not charged.

Further, for the record, Applicants respectfully disagree with the Office's assertion that the Stürzebecher $-CH_2OH$ group, rather than the amidine group, is positively charged. The pK_a of an amidinium group is $\sim 12-13$, rendering this functional group a strong base. By contrast, the pK_a of a protonated alcohol ROH_2^+ is ~ -2 , rendering this functional group a strong acid. The amidine group is therefore $\sim 10^{14}-10^{15}$ times more basic than the $-CH_2OH$ group, and it is this functional group that is charged in the Stürzebecher compound. The Stürzebecher benzylamidinium group corresponds to substructure $-Y(-R_1)-V-U-z$ of instant formula I, and each of R_1 , R_2 , R_3 , and R_5 is therefore uncharged. Consequently, the Stürzebecher compound is not encompassed by the instant claims.

In further support of the arguments presented herein, Applicants attach a Declaration by Andrea Schweinitz, an inventor of both the instant application and Stürzebecher, attesting to the structural and chemical features of the Stürzebecher compound.

Claims 34 and 35 are directed to salts of the compound of claim 21. Claim 36 is directed to a method of preparing the compound of claim 21. Claims 37 and 38 are directed to pharmaceutical compositions that include the compound of claim 21. Because Stürzebecher does not anticipate claim 21, this reference similarly does not anticipate claims 34-38. Applicants respectfully request withdrawal of this ground for rejection.

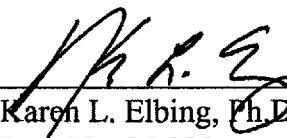
CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the final Office action for two months, to and including June 30, 2009, and payment of the required extension fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 30 June 2009



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jorg Stürzebecher et al. Confirmation No.: 1588
Serial No.: 10/506,579 Art Unit: 1621
Filed: April 13, 2005 Examiner: P. Zucker
Customer No.: 21559
Title: UROKINASE INHIBITORS, PRODUCTION AND USE THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ANDREA SCHWEINITZ UNDER 37 C.F.R. § 1.132

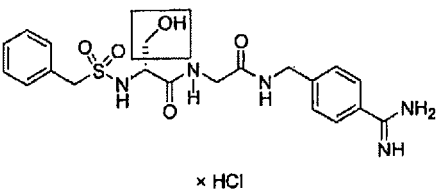
TRAVERSING GROUNDS OF REJECTION

Under 37 C.F.R. § 1.132 and regarding the rejection of claims 21 and 34-38 in view of Stürzebecher (DE 10029014-A1) ("Stürzebecher"), I declare:

1. I am an inventor of the subject matter that is described and claimed in the above-captioned patent application.

2. I am an inventor of the subject matter that is described and claimed in Stürzebecher.

3. As recited in pending claim 21, one or more of R_1 , R_2 , R_3 , or R_5 in formula I must be charged. A compound that has a charged group at R_4 would not be encompassed by the claims if R_1 , R_2 , R_3 , and R_5 were each uncharged. The Office has cited the compound described in paragraph [0025] of Stürzebecher, benzylsulfonyl-D-Ser-Gly-4-Amidino-benzylamide \times HCl ("the Stürzebecher compound"). As shown in the following table, the Stürzebecher benzylamidine does not correspond to any of R_1 , R_2 , R_3 , or R_5 in formula I and the Stürzebecher $-CH_2OH$ corresponds to R_4 in formula I:

<p>Stürzebecher compound:</p>  <p style="text-align: center;">x HCl</p>	<p>Corresponding Groups in Instant Formula I:</p> <p> $R_1 = \text{H};$ $R_2 = \text{H};$ $R_3 = \text{H};$ $R_4 = -(\text{CH}_2)_f\text{OR}_{11}$, where $f=1$ and R_{11} is H; $R_5 = -\text{SO}_2\text{R}_{12}$, where R_{12} = unsubstituted aralkyl; $\text{U} = \text{phenyl};$ $\text{V} = (\text{CH}_2)_n$, where $n = 0$; $\text{X} = \text{CH};$ $\text{Y} = (\text{CH}_2)_m$, where $m = 1$; and $\text{Z} =$ occurs in the 4-position and is an amidino group $-\text{C}(\text{NH})\text{NHR}_{14}$, where R_{14} is H. </p>
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In this structure, R_1 , R_2 , and R_3 are each H and R_5 is $\text{SO}_2\text{CH}_2\text{Ph}$, and none of these groups is charged. The Stürzebecher compound is therefore not encompassed by the claimed chemical genus.

4. A chemist would know that the amidine group is the most basic group in the Stürzebecher compound. Consequently, a chemist would recognize that the $-\text{CH}_2\text{OH}$ group is neutral and the amidine group is positively charged. None of the R_1 , R_2 , R_3 , or R_5 groups in the Stürzebecher compound is charged.

5. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

30.06.2009
Date

Andrea Schweinitz
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